

NOV 24 2003

510(k) Summary of Safety and Effectiveness

Date: October 30, 2003**Submitter:** GE Medical Systems - *Information Technologies*
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Milwaukee, WI 53223 USA**Contact Person:** Lisa Lee Michels
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GE Medical Systems - *Information Technologies*
Phone: (262) 293-1705
Fax: (414) 918-8112**Trade/Proprietary Name:** MAC 5000 ECG Analysis System**Common/Usual Name:** Electrocardiograph**Classification Names & Citations:**

21 CFR 870.1425	Programmable diagnostic computer	74DQK
21 CFR 870.2920	Transmitters and Receivers, Electrocardiograph, Telephone	74DXH
21 CFR 870.2340	Electrocardiograph	74DPS
21 CFR 870.2340	System, ECG Analysis	74LOS
21 CFR 870.1025	Detector and Alarm, Arrhythmia	74DSI

Predicate Devices: Mac 5000 Rest ECG Analysis System with ST Option (K014108).

All algorithms have been previously cleared and include:
ECG Analysis Program 12SL (K002209)
Phi Res Algorithm (K972199)

Device Description: The Mac 5000 ECG Analysis System is designed to acquire, analyze, display, and record ECG signals from surface ECG electrodes. The device consists of two basic components: the processing unit and patient acquisition module. Models provide rechargeable battery operation and/or optional trolley for transporting the equipment.

The MAC 5000 can deliver 3, 6, 12, or 15 lead ECG's, 12 lead interpretive analysis, vector loops, and can be upgraded to provide software analysis options such as high resolution signal averaging of QRS and P wave portions of the electrocardiogram. Transmission and reception of ECG data to and from a central ECG cardiovascular information system is optional.

The MAC 5000 system acquires ECG data using a modular patient

data acquisition device called the CAM14 (K991735). By placing the data acquisition device closer to the patient, signal fidelity is improved and noise is reduced. MAC 5000 delivers 12 or 15 lead ECG's on full-size reports with alphanumeric keyboard for patient demographic and other data entry, a full-size VGA graphics and waveform display, integrated thermal writer and removable data storage.

Additionally, the MAC 5000 utilizes battery power for customer convenience and can transmit and receive ECGs to and from a central ECG cardiovascular information system via optional communication links. The system is intended as a mobile device but the main unit can be separated from the trolley and used as a desktop unit.

Intended Use:

The MAC 5000 ECG Analysis System is intended to be used under the direct supervision of a licensed healthcare practitioner. The MAC 5000 is intended to be used by trained operators in a hospital or medical professional's facility environment to record ECG signals from surface electrodes. The device is intended to acquire, analyze, display, and record electrocardiographic information from adult and pediatric populations.

Technology:

The technological characteristics of the MAC 5000 device have been updated to reflect use of current technology and to incorporate user-requested features. Data in this submission demonstrate that these technological characteristics do not raise new questions of safety or effectiveness.

Test Summary:

The MAC 5000 complies with the voluntary standards as detailed in Section 9 of this submission.

The following quality assurance measures were applied to the development of the MAC 5000.

- Requirements specification reviews
- Code inspections
- Software and hardware testing
- Safety testing
- Environmental testing
- Final system validation

Conclusion:

The results of these measurements demonstrate that the MAC 5000 is as safe, effective, and performs as well as the predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 24 2003

GE Medical Systems Information Technologies
c/o Ms. Lisa Lee Michels
Regulatory Affairs Specialist
8200 West Tower Avenue
Milwaukee, WI 53223

Re: K033492

Trade Name: MAC 5000 ECG Analysis System

Regulation Number: 21 CFR 870.1025

Regulation Name: Patient Physiological Monitor (arrhythmia detector and alarm)

Regulatory Class: Class III (three)

Product Code: MHX

Dated: October 30, 2003

Received: November 4, 2003

Dear Ms. Michels:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

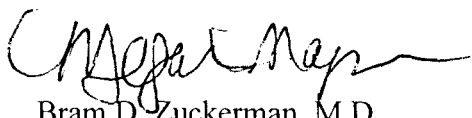
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

for 
Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): Unknown;

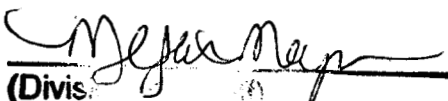
510(k) filed on 13 December, 2001

Device Name: MAC 5000 ECG Analysis System**Indications For Use:**

The MAC 5000 ECG Analysis System is intended to acquire, analyze, display, and record electrocardiographic information from adult and pediatric populations. Basic systems deliver 3, 6, 12, or 15 lead ECG's, 12 lead interpretive analysis, vector loops, and can be upgraded to provide software analysis options such as high resolution signal averaging of QRS and P wave portions of the electrocardiogram. Transmission and reception of ECG data to and from a central ECG cardiovascular information system is optional.

The MAC 5000 is intended to be used under the direct supervision of a licensed healthcare practitioner, by trained operators in a hospital or medical professional's facility.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division)
Division: Cardiovascular Devices510(k) Number K033492Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)